510(k) Summary

JUL 2 3 2013

Device Trade Name: Frag-Loc® System

Manufacturer:
Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Contact:
Ms. Kara Budor
Regulatory Specialist
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Prepared by:
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Date Prepared: July 22, 2013

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Codes: HTN; HWC

Indications For Use:
The Frag-Loc® System is intended to provide compression to bones and bone fragments for the fixation of fractures, fusions, or osteotomies.

Device Description:
The Frag-Loc® System consists of various sizes of screws, sleeves, and washers which are implanted from opposite ends of a bone in order to provide compression to bones and bone fragments for the fixation of fractures, fusions, or osteotomies.

Predicate Device:
The subject Frag-Loc® System is substantially equivalent to the predicate Trans-Osseous Bolt (K982354) with respect to intended use, geometry, and method of fixation. Although the materials in these systems differ, both are made of biocompatible metals and the testing summarized in the Design Control Activities Summary demonstrates that the Frag-Loc® System met the pre-determined acceptance criteria for the verification activities.

Preclinical Testing:
The new Frag-Loc® System components were subjected to axial pull-out and 4-point bend testing to characterize their strength. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

Acumed, LLC
% Ms. Kara Budor
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K130986
Trade/Device Name: Frag-Loc® System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HWC
Dated: June 7, 2013
Received: June 10, 2013

Dear Ms. Budor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K130986

Device Name: Frag-Loc® System

The Frag-Loc® System is intended to provide compression to bones and bone fragments for the fixation of fractures, fusions, or osteotomies.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori A. Wiggins

Division of Orthopedic Devices